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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,687	11/20/2001	Sean V. Tavtigian	2318-380	9081

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EXAMINER
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RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/988,687

Applicant(s)

TAVTIGIAN ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

1. Claims 1-3 are pending in the application and are currently under prosecution.

### ***Information Disclosure Statement***

2. The information disclosure statement filed November 20, 2001 in Paper No. 3 is acknowledged, but it fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

However, MPEP § 609 states that the Examiner will consider information that has been considered by the Office in a parent application when examining a divisional application filed under 37 CFR § 1.53(b). Such information need not be resubmitted in the continuing application unless applicant desires the information to be printed a patent issuing upon the continued application.

In addition, MPEP § 609 states that for divisional applications filed under 37 CFR § 1.53(b), in order to ensure consideration of information previously submitted, but not considered, in a parent application, applicant must resubmit the information in the continuing application in compliance with 37 CFR §§ 1.97 and 1.98.

As the information provided in the information disclosure statement filed November 20, 2001 was considered in the parent application, there is no need to resubmit the information in this application, unless the applicant desires the information be printed on the patent, in which case the submission must comply with 37 CFR § 1.98(a)(2). To comply with 37 CFR 1.98(a)(2), a submission must contain a legible copy of each U.S. and foreign patent, each publication, or that portion which caused it to be listed, and all other information or that portion which caused it to be listed.

### ***Specification***

3. The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code and to the Internet contents

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so identified. Reference to hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified is impermissible and therefore requires deletion.

See pages 82 and 90, for examples of attempts to incorporate information by reference to hyperlinks and to the Internet websites so identified or assessed.

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding acceptable incorporation by reference.

4. The specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of improperly demarcated trademarks or service marks include Autogen™ (page 65), Dynal™ (page 66), GenBank® (page 66), Promega™ (page 69), Bigdye™ (page 71), Platinum™ (page 71), and American Type Culture Collection™ (page 86).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. As a preliminary note to the following grounds of rejection, the claims recite an intended use for a product, namely a kit comprising a primer. The recitation of an intended use for a claimed product is not given weight in comparing the claimed product with products of the prior art. Accordingly, claims 1-3 read on a kit comprising primers.

Additionally, it does not appear that "kit" is explicitly defined, nor is an exemplary "kit" described in the specification. However, Merriam-Webster's Online Dictionary, 10th Edition, defines "kit" as "a set of tools or implements" ([© 2003 by Merriam-Webster, Incorporated](#)). Accordingly the claims are drawn to a collection of tools or implements comprising primers, and any disclosure of "primers" is therefore deemed anticipatory of the claimed invention.

Nevertheless, the following note is also made:

The claims are drawn to a kit comprising primers for sequencing or amplifying a region of "HPC2". The specification defines "HPC2 allele" as a normal allele of the HPC2 locus at page 23; "HPC2 locus", "HPC2 gene", "HPC2 nucleic acids", "HPC2 polynucleotide" are defined at page 23 of the specification as polynucleotides in the HPC2 region; and "HPC2 region" is defined at page 26 as a portion of chromosome 17. However, it appears that italicized term "*HPC2*" is not defined in the specification. Accordingly, given the broadest interpretation, the claims are drawn to a kit comprising primers for sequencing or amplifying a region of chromosome 17 between markers

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D17S947 and D17S799, the polynucleotide sequence of which has an open reading frame encoding a polypeptide having at least 541 amino acids.

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,075,216-A.

US Patent No. 5,075,216-A ('216) teach a kit comprising primers (claim 26); therefore, all of the limitations of the claims have been met by the teachings of the prior art.

Nonetheless, the primers disclosed by '216 include, for example, any that hybridizes to an M13 cloning vector and is suitable for sequencing cloned inserts in M13 and/or pUC-based vectors (claim 30). At page 71, for example, of the present specification, M13 forward and reverse primers are disclosed as examples of primers used to sequence the HPC2 gene (Example 8). Accordingly, it appears that the prior art teaches primers suitable for sequencing the region of *HPC2* encoding amino acid 217 and/or amino acid 541, and although the prior art does not teach the use of the primers to amplify a region of *HPC2* by "allele specific polymerase chain reaction", it is believed the primers could be used to amplify a DNA molecule inserted into an M13 or pUC-based cloning vector.

8. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,780,263-A.

US Patent No. 5,780,263-A ('263) teach primers. As the claims are drawn to a "kit" or "a set of tools or implements" *comprising* primers, the limitations of the claims are thus met.

Nonetheless, '263 teach two primers, namely M13 forward and reverse primers, which '263 discloses were used to amplify a portion of a DNA molecule for sequencing. The polynucleotide sequences of these primers is disclosed in the specification in column 20, lines 55-60. The present specification discloses that identical primers can be used to sequence a full-length human HPC2 cDNA (page 67, Table 5).

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Additionally, '263 discloses a kit containing random sequence primers, and '263 teaches these primers are used for sequencing (column 20, lines 60-63). This kit of random sequence primers contains multiple primers that are complementary to a region of HPC2, including a region of *HPC2* comprising the codon encoding amino acid 217 or amino acid 541.

9. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang, et al (Science 280: 1077-1082, 1998), as evidenced by Exhibit 1, which is information retrieved from Internet resources at <http://www.ncbi.nlm.nih.gov/genome/guide/human/>.

Wang, et al teach primers. As the claims are drawn to a "kit" or "a set of tools or implements" *comprising* primers, the limitations of the claims are thus met.

Nonetheless, Wang, et al teach primers that can be used to amplify a marker designated G4297. This marker is located on human chromosome 17 between markers D17S947 and D17S799 as evidenced by Exhibit 1. Therefore, absent a showing of any difference, the primers disclosed by Wang, et al are deemed the same as the primers of the instant claims, since the primers of Wang, et al could be used to sequence or amplify a region of *HPC2*.

The Office, however, does not have the facilities for examining and comparing an applicant's product with a product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as applicant's product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed product is different than a product taught by the prior art.

### ***Conclusion***

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

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(703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

  
STEPHEN RAWLINGS

slr  
May 2, 2003